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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,817	01/23/2002	Rudolph E. Tanzi	0609.4460005	4182
26111	7590	03/10/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			WOITACH, JOSEPH T	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,817

Applicant(s)

TANZI ET AL.

Examiner

Joseph T. Woitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/15/2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-10,12,13 and 27-29 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-10,12,13 and 27-29 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 23 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

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DETAILED ACTION

This application is a divisional of US Application 09/241,606, filed February 2, 1999, now US Patent 6,472,140, which is a continuation in part of Application 09/148,503, filed September 4, 1998, now US Patent 6,342,350, which claims priority to US provisional applications 60/057,655, filed on September 5, 1997 and 60/093,297, filed on July 17, 1998.

Applicants amendment filed December 15, 2004, has been received and entered. The specification has been amended. Claims 1, 11, 14-26, 30-76 have been cancelled. Claims 2-10, 12, 13 and 27-29 are pending and currently under examination.

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on June 16, 2004 was acknowledged. The restriction requirement between Groups I and II was withdrawn. No new arguments have been presented, and it is noted that claims withdrawn to the non-elected invention have been cancelled.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-10, 12, 13, 27-29, drawn to a therapeutic agent for combating Alzheimer's disease wherein the agent can replace and/or supplement α_2 M function is currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

The amendment to the specification to list the priority documents has addressed the issue regarding the claim for priority.

Specification

The amendment to the specification to indicate the specific SEQ ID NO in figure 6 has addressed the issue of sequence compliance. This application complies with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-10, 12, 13 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Specifically, the amendment to the claims reciting that the claimed

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molecule "does not comprise SEQ ID NO: 4" is considered new matter. The support in the specification pointed to by Applicants is noted. However, there is nowhere in the cited portions of the specification, nor upon search and review of the entire specification literal support for excluding SEQ ID NO: 4 from the claimed invention. In contrast to the claim limitation to not include SEQ ID NO: 4, on page 25, starting at line 27, one of the contemplated embodiments of the invention is a "peptide composed of the entire A β and LRP binding domains of α_2 M (SEQ ID NO: 4)". Finally, review of the original claims does not provide literal nor figurative support for the new amendment. Accordingly, since the instant specification considers the sequence one of the contemplated embodiments and there is no literal support to exclude the sequence, the recitation of "does not comprise SEQ ID NO: 4" is considered new matter.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 2-10, 12, 13 and 28 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed,

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involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-10, 12, 13 and 28 rejected under 35 U.S.C. 102(b) as being anticipated by NCBI entry CAA 01532 (August 22 1994) is withdrawn.

The amendment to the claims has differentiated the claimed invention from that taught in NCBI of human alpha 2 macroglobulin. Specifically, the claims now exclude the specific sequence present in CAA 01532.

Claims 27 and 29 rejected under 35 U.S.C. 102(b) as being anticipated by NCBI entry CAA 01532 (August 22 1994) is withdrawn.

Applicants not the requirements for anticipation under 35 USC 102, and argue that the cited reference does not teach on or more pharmaceutically acceptable carriers" as recited in the

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claims. See Applicants' amendment, pages 11-12. Applicants arguments have been fully considered, and found persuasive.

Specifically, the NCBI disclosure only provides the protein sequence without providing any other context for the protein. As noted by Applicants, the reference does not teach all the limitations required by the instant claims.

Claims 2-10, 12, 13 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Esper *et al.* (WO 91/03557).

The amendment to the claims to indicate that SEQ ID NO: 14 is excluded from the claimed embodiments is noted. Further, claims 27 and 29 are drawn to an anti-LRP- α B molecule, wherein claim 29 specifically indicates that it is either SEQ ID NO: 4 or SEQ ID NO: 14. It is noted that the specification does not define α_2 M to be the entire A β binding domain and an entire LRP binding domain, nor does the claims require this. In interpreting the breadth of the instant claims, a reasonable interpretation would be any anti-LRP- α B peptide, that binds to any portion of the LRP- α B would anticipate the claims. In this case, the human alpha 2-macroglobulin would bind to α_2 M and be considered an anti-LRP- α B.

Esper *et al.* teach alpha 2-macroglobulin, and homology searches indicate that the sequences include and comprise SEQ ID NOs: 4 and 14. Esper *et al.* teach the use of the protein in replacement therapy, therefore provide pharmaceutically acceptable carries for a composition comprising α_2 M. To the extent that claims 2-10, 12, 13 and 28 specifically exclude the use of SEQ ID NO: 14, it is noted that Esper *et al.* teach and claim variants, fragments and derivatives of alpha 2-macroglobulin, therefore provide the teachings that sequences other than

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SEQ ID NO: 14 are contemplated and can be used. Again it is noted that upon review of the specification the specific sequences set forth are those previously known in the art for alpha 2-macroglobulin (for example page 25, starting on line 25).

Conclusion

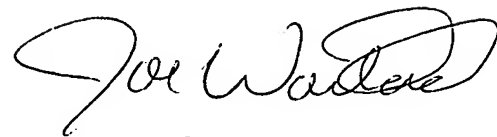
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


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